Preventive Medicine Reports 29 (2022) 101968

Contents lists available at ScienceDirect

Preventive Medicine Reports

journal homepage: www.elsevier.com/locate/pmedr

Short communication

User-centered approach in the development of an eHealth tool for self-management skills in functional insulin therapy to prevent complications of diabetes

Cécile Fezzi [a,1], Hélène Refahi [a,1], Eliane Albuisson [b], Eva Feigerlova [a,c,d,*]

[a] Department of Endocrinology, Diabetology and Nutrition, Centre Hospitalier Universitaire and Medical Faculty, Université de Lorraine, Nancy 54000, France
[b] DRCI, Département MPI, Unité de Méthodologie, Data Management et Statistique UMDS, Centre Hospitalier Universitaire and Medical Faculty, Université de Lorraine, Nancy 54000, France
[c] INSERM UMR_S 1116 - DCAC, Université de Lorraine, Nancy 54000, France
[d] Centre universitaire d'enseignement par simulation (CUESiM), Hopital virtuel de Lorraine, Faculté de médecine, Nancy F-54000, France

ARTICLE INFO

Keywords:
Type 1 diabetes
eHealth
Patient participation
Self-management
Functional insulin therapy

ABSTRACT

One of the biggest tasks for health professionals is to address the needs of persons with chronic illnesses like type 1 diabetes (T1D) and to support the acquisition of all necessary self-management behaviors. Functional insulin therapy (FIT) enables patients to adapt insulin doses according to everyday situations and reduces the risk of complications of diabetes.

The aim was to describe the co-development, with patient as partners, of an eHealth tool for the acquisition of skills in FIT, to evaluate the user's acceptability and learning effectiveness on a sample of T1D patients followed in the University Hospital of Nancy. Subjects were invited to participate between July and August 2020.

A total of 35 participants from different professional categories, median age of 41 years (IQR 27; 60) were included. In 22 subjects having access to all learning activities, there were positive relationships between the success score and the task (Spearman's rank correlation coefficient $r_s = 0.5$), between the intent to use and following parameters: perceived utility ($r_s = 0.694$), educational adequacy ($r_s = 0.786$), tasks $r_s = (0.664)$, technology ($r_s = 0.520$) and ease of use ($r_s = 0.659$).

This pilot study describes a user-centered approach to development of an eHealth tool for the acquisition of self-management skills in FIT. The online tool was well accepted and showed a positive impact on learning. The concept presented here will be useful to prompt future eHealth interventions in T1D or other chronic conditions aiming to increase patients' autonomy to prevent disease-related complications.

1. Introduction

One of the tasks for health professionals is to address the needs of persons with type 1 diabetes (T1D) and to support the acquisition of self-management behaviors by patients and/or their caregivers. Intensified insulin therapy with a goal of maintaining blood glucose concentration close to normal range is the cornerstone of the modern therapy for T1D (The Diabetes Control and Complications Trial Research Group, 1993). Nowadays we dispose different tools that enable almost physiological glycemic control: continuous glucose monitoring (Langendam et al., 2012), sensor-augmented insulin pump (Bergenstal et al., 2013) or an automated insulin delivery system ("closed loop") (Elleri et al., 2011). However, current technologies remain hybrid and cannot predict situations requiring the adaptation of insulin doses such as meals, sport activities, stress or unstable diabetes. Patients' active involvement in daily self-management is necessary (Elleri et al., 2011). Educational approaches for self-management skills are mandatory to prevent the risk of iatrogenic hypoglycemia, acute and long-term complications.

Functional insulin therapy (FIT) is an optimized intensified insulin therapy, whose objective is to faithfully reproduce the physiological secretion of insulin. It is based on three principles: 1/ a separate management of basal and prandial insulin; 2/ the adaptation of insulin doses

* Corresponding author at: Department of Endocrinology, Diabetology and Nutrition, Nancy, Centre Hospitalier Universitaire, Université de Lorraine, Nancy 54000, France.
E-mail addresses: eva.feigerlova@fulbrightmail.org, eva.feigerlova@univ-lorraine.fr (E. Feigerlova).
[1] Equal contribution.

https://doi.org/10.1016/j.pmedr.2022.101968
Received 19 March 2022; Received in revised form 9 August 2022; Accepted 25 August 2022
Available online 30 August 2022

to every-day situations and; 3/ the use of additional correction boluses of insulin in case of hyperglycemia. It is associated with a reduction of the risk of severe hypoglycemia, ketoacidosis and with a better quality of life (DAFNE Study Group, 2002). To apply the principles of FIT, patients have to acquire specific knowledge for self-management behaviors. Therapeutic education in FIT is time- and money-consuming and cannot be offered to all patients. Therefore, eHealth strategies seem a promising alternative. To be accepted by users, eHealth learning modalities should incorporate patients' perspectives (OHTAC, 2015).

In collaboration with T1D patients as partners, we developed an eHealth tool on the acquisition of skills in FIT. The goal is to provide a remote teaching tool available on the hospital's website, which enables the T1D patient to acquire the necessary knowledge for self-management skills in FIT, and the health professional to deliver a personalized care. The aims of the present study were to describe the workflow of the development of eHealth tool with patients as partners including the evaluation of learning effectiveness and users' acceptability.

2. Methods

This is an exploratory observational study conducted in the Department of Endocrinology of the University Hospital of Nancy. Patients were involved in all stages of the development process (Supplementary Fig. 1): 1/ design; 2/ elaboration of educational content; 3/ reviewing and adaptation of the pilot version; 4/ acceptability study; 5/ post-review of a pilot-tested version.

2.1. eHealth tool

An eHealth learning tool baptized "MyFIT" (*My Functional Insulin Therapy*) was developed between June 2018 and June 2020 by the team of investigators in collaboration with five T1D patients (3 women) as partners, from four different age categories according to the use of Internet (<25 years, 25–39 years, 40–69 years, > 70 years) (Statista Research Department, 2021). Development was carried out based on the principles of FIT (Bendik et al., 2009; Grimaldi et al., 2008) and the conventional learning module provided in a hospital setting (Flaus-Furmaniuk et al., 2017). Learning content was adapted to online education (Arbaugh and Hornik, 2006). User is guided by a mascot according to his/her age category (child/adolescent, adult, elderly), gender and socio-professional activities. The eHealth tool comports two parts: 1/ Module 1 general knowledge on diabetes and self-management which is prerequisite for the acquisition of skills for FIT; 2/ Module 2 acquisition of self-management skills for FIT including coefficients of FIT and carbohydrate counting (Table 1). Both modules contain interactive activities and exercises from everyday life situations promoting self-management behaviors. Automatized feedback messages are generated upon answering knowledge questions. Progress bars enable the users to follow their learning. Statistical reports generated by the tool enable health professionals to calculate the scores on knowledge tests and guide their patients.

2.2. Acceptability study

Adult patients with T1D on intensive insulin therapy for >1 year, who received standard diabetes education with a fix meal eating plan by the diabetes team, were invited by telephone by the investigator (EF) between July 25, 2020 and August 7, 2020 to participate: a/ complete e-learning activities of the eHealth tool including knowledge questionnaires; b/ complete the user's acceptance self-administered questionnaire. To access the eHealth tool on Internet, a code was sent to each participant via e-learning platform of the University Hospital of Nancy. The length of participation was a time needed to complete learning activities and self-administered questionnaire. Last answers of the participants were received on September 30, 2020.

Evaluation of the acceptability of the eHealth tool was carried out according to the recommendations of the Association of American Medical Colleges (Association of American Medical Colleges, 2007) following the model of Kirkpatrick (Kirkpatrick and Kirkpatrick, 2006) with two levels that the learner can reach: i/ learning effectiveness as a success rate on the knowledge tests; ii/ evaluation of the user's behavior and of the perceived performance according to the acceptance model of the technology (Gagnon et al., 2012) (Supplementary Table 1): a/ perceived utility; b/ perceived ease of use; c/ intention to use; d/ adequacy of learning. The user acceptance was evaluated using a self-administered questionnaire, elaborated by the investigators, which contained a voluntary section for respondents to submit any free commentaries about their experience with using the eHealth tool. A final revision of the pilot-tested version was undertaken in collaboration with five patient-partners including an external review provided by the health professionals (1 dietitian, 1 diabetologist, 1 nephrologist) (Supplementary Fig. 1). The study follows the STROBE guidelines (von Elm et al., 2007) (Supplementary Table 3).

2.3. Ethics

The study was approved by the IRB of the University Hospital of Nancy (n° 360). It is registered at ClinicalTrials.gov (NCT04512885) and at French National Commission for Data Protection and Liberties (n° 2020PI162-49). All subjects received verbal and written information regarding the study objectives, voluntary participation, and assurance of confidentiality. All data were anonymized before the start of the analysis.

2.4. Statistical analysis

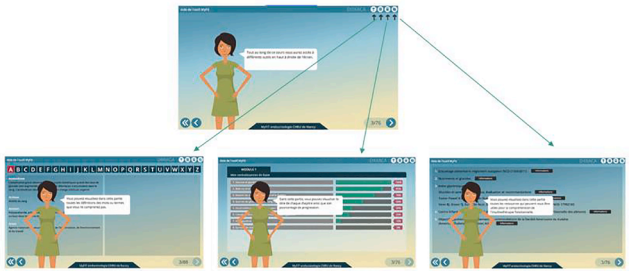
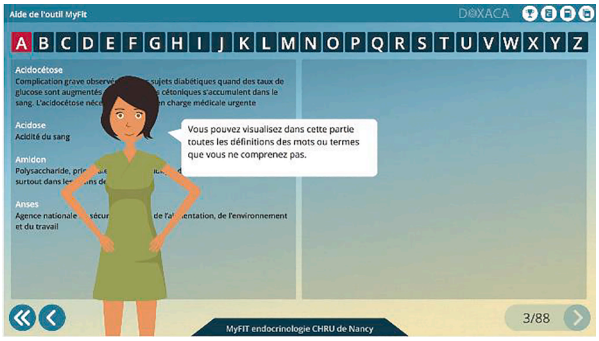
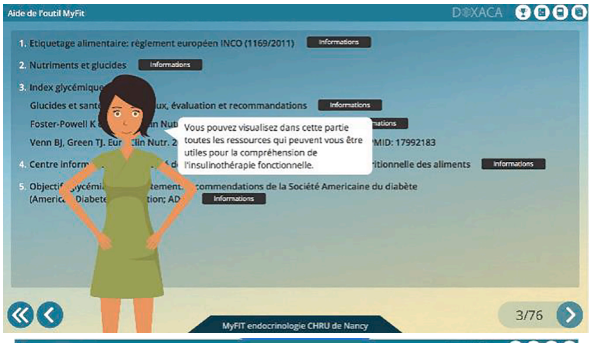
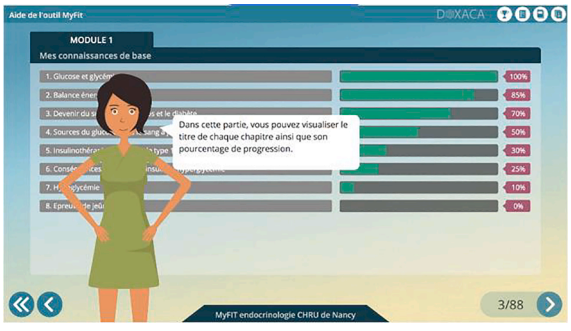
All quantitative variables are described as medians and percentiles (IQR, 25–75th percentile), all proportions as percentages with 95 % confidence intervals. The final scores on the MyFIT knowledge tests (Modules 1 and 2) were calculated as a percentage of the overall score for all exercises. The maximum score that could be obtained was 100 %. More than 75 % users should answer the questions correctly. The expected success rate was of 88 % ± 12 %. A total of 30 subjects was necessary, taking into account 5 % lost to follow-up. Correlations were measured, using a Spearman's rank correlation, between the dimensions of the self-administered questionnaire and the scores on the knowledge tests. Non parametric comparisons were two-sided. Alpha risk was set at 0.05. Free form answers were coded and analyzed thematically by two investigators and any discrepancies were resolved by consensus with two other investigators (Fitzpatrick and Boulton, 1994).

3. Results

Out of 63 subjects eligible for inclusion, 35 patients agreed to participate. The Module 2 was accessible to 22 out of 35 participants due to technical problems which were difficult to resolve in the context of the COVID-19 epidemics. These technical difficulties are currently resolved. Demographic characteristics of the participants are shown in Table 2. Median age of the study population (n = 35, 46 % males) was 41 years (IQR 27; 60). All patients were on intensified insulin therapy (more than 80 % on insulin pump). The participants were from different professional categories and all of them had a high school diploma or university degree.

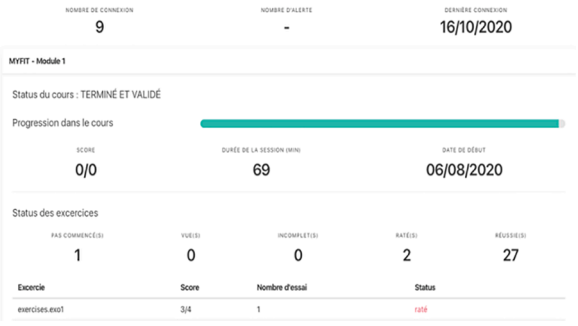
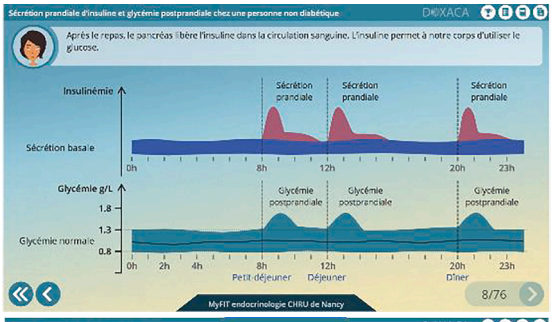
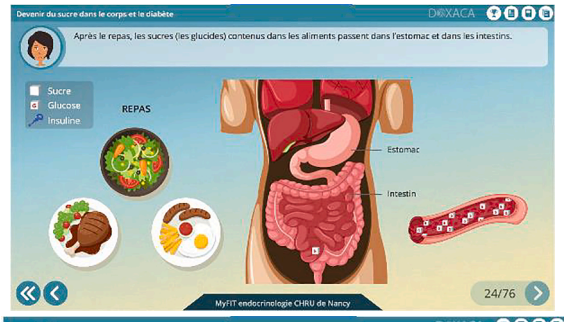
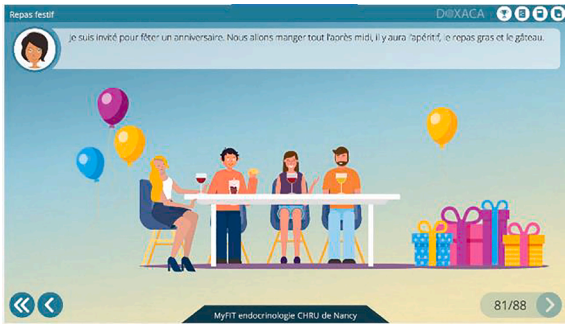
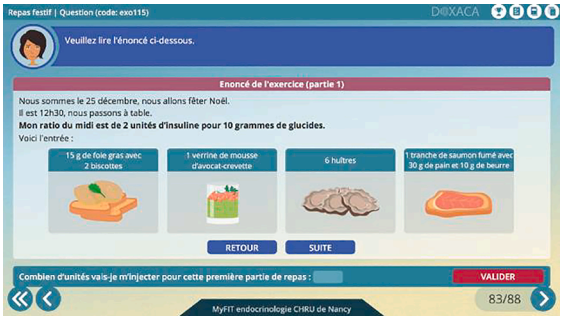
A final success score in 22 patients, who could complete all learning activities and evaluation exercises of Module 1 and Module 2 was in median of 85.6 % (IQR: 79.2; 91.4). Among these 22 participants, 90 % had a final score higher than 78 %. Results of the user's acceptance self-administered questionnaire are detailed in Table 2**.** There was a positive relationship between the success score (Module 1 and Module 2) and the task (Spearman's rank correlation coefficient $r_s = 0.454$; $P = 0.039$). We observed a positive relationship between the intent to use and the

Table 1
MyFIT tool: learning activities and navigation.

Easy navigation guided by a mascot:	
Personalized learning: six *mascots based on age, gender and socio-professional activities of learners*	
Access to glossary	
Access to online resources	
Visual progression bar	
Timely and appropriate feedback from health-care providers	

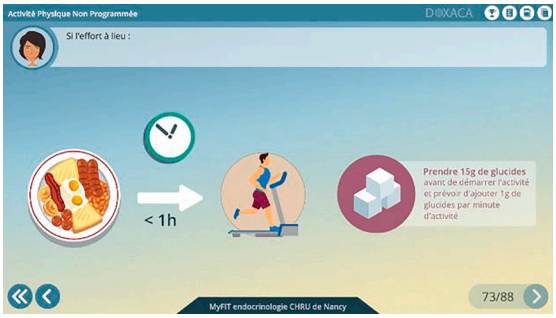
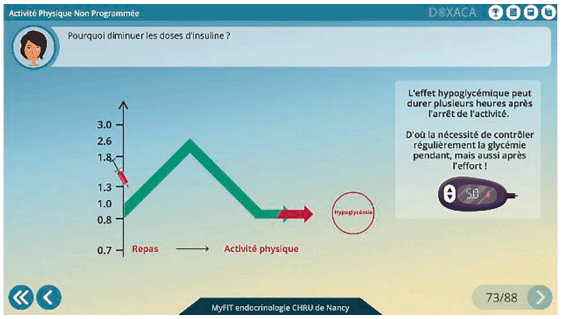
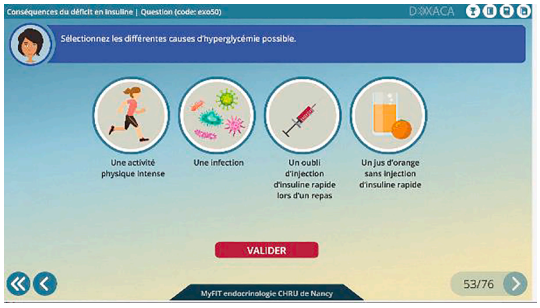
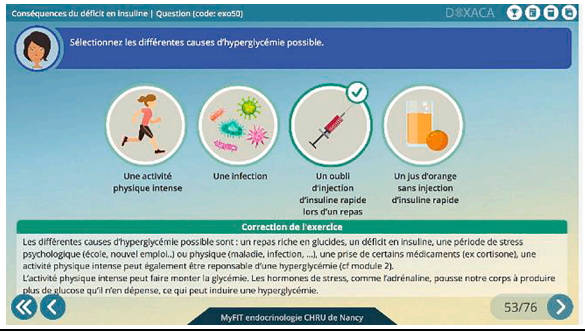
(*continued on next page*)

Table 1 (*continued*)

Interactive lessons with animations	  
Active learning: *exercises based on every-day life situations*	 

(*continued on next page*)

Table 1 (*continued*)

Physical activity: *exercises adapted to age and professional activities of learners*	
	
Respect of diverse ways of learning: *concept of "rapid e-learning blog " - access to learning module or directly to knowledge evaluation*	
	
	

following parameters: perceived utility ($r_s = 0.694$; $P = 0.001$); educational adequacy ($r_s = 0.786$; $P = 0.001$); tasks $r_s = (0.664$; $P = 0.001)$; technology ($r_s = 0.520$; $P = 0.002$); ease of use ($r_s = 0.659$; $P = 0.001$). Thirty-two questionnaires contained free-text comments from the study participants (91 %). The answers were abstracted into three main categories: e-learning environment, interface and navigation, and learning content. Major themes and representative responses are illustrated in Supplementary Table 2.

We further investigated whether there were any differences between the group of 13 subjects who experienced connection problems and the group of 22 subjects who completed all learning activities. There were no difference in age ($P = 0.649$) or sex ($P = 0.968$). No significant

Table 2
Sociodemographic characteristics of the population and answers to a self-administered questionnaire evaluating users' acceptance.

	Groups of participants	
	Module 1 (n = 13)	Modules 1 + 2 (n = 22)
Sex (female)	6 (7)	10 (12)
Age (year)	41 (27; 55)	41 (36,5; 60)
Duration of diabetes (years)	19 (13; 36)	23 (19; 31)
HbA1c (%)	8 (7,4–8,3)	7,2 (6,9–7,8)
Insulin pump (% of patients)	77 %	85 %
Duration of training (min)		
Module 1	41 (27; 55)	80 (64; 113)
Module 2	–	219 (146; 387)
Module 1 + Module 2	–	284 (245; 473)
Success score (%)		
Module 1	93 (79,3; 93,1)	93 (86,1; 96,6)
Module 2	–	83,9 (79,6; 89,7)
Module 1 + Module 2	–	85,6 (79,2; 91,4)
Users' acceptance (Answers) *		
I feel comfortable with new technologies	4 (4; 5)	5 (4; 6)
I use e-learning tools	4 (2; 4)	4 (3,3; 5,8)
It is convenient to do distance training	4 (4; 5,5)	6 (5; 6)
Connection to the tool is easy	5 (4; 6)	5 (4; 6)
Navigation is easy	5 (4; 5)	5 (4; 6)
I feel comfortable with this tool	5 (4,5; 5)	5 (4; 5)
I will need a technical assistance to be able to use this tool	1 (1; 2,5)	1 (1; 1)
I can easily find different functions of the tool	4 (4; 5)	5 (5; 6)
The tool is pleasant to use	5 (4; 5)	5 (4; 6)
Images and mascots are user-friendly	5 (4; 5)	5 (4,3; 6)
Course content is easy to follow	5 (5; 5)	5 (4; 5)
The content of the glossary is relevant	5 (4,5; 5)	5 (5; 6)
Internet resources are adapted	5 (4; 5)	5 (4; 6)
I find easily the information I need	5 (4; 5)	5 (4; 5)
I will use this tool frequently	4 (4; 5,5)	6 (4; 6)
I feel confident to apply the acquired knowledge	5 (5; 5)	5 (4; 5,6)
This tool will help me in my everyday life	5 (4,5; 5,5)	5 (4; 5,6)
The proposed exercises are practical	5 (4; 5)	5 (4; 6)
I will use this tool to manage my disease	5 (3,5; 5)	5 (4; 5,8)
The tool will allow my relatives to help me to manage my disease	3 (2; 4,5)	4 (2,3; 6)
I did the training not to disappoint my doctor	1 (1; 1)	1 (1; 1)
The tool will enable patients to learn how to manage their disease	5 (4; 5,5)	5 (5; 6)
The tool will help healthcare professionals to take care of their patients	5 (4,5; 5,5)	5 (4; 6)
The tool will allow me to update my knowledge	5 (5; 5,5)	6 (5; 6)
The items are logically presented	5 (4,5; 5,5)	6 (5; 6)

Values expressed as median (IQR) or as percentage.
*Answers on 6-point Likert-scale: 1 = strongly disagree 2 = disagree, 3 = somewhat disagree, 4 = somewhat agree, 5 = agree, 6 = strongly agree. Values expressed as median (IQR).

differences were observed for the time spent on the first module ($P = 0.102$), knowledge score of the first module ($P = 0.20$) or dimensions of the self-questionnaire except for internet use ($P = 0.048$). The evaluation of Internet is biased given the recurring connection problems encountered by the group of 13 subjects during the COVID-19 epidemics. These results suggest that the connection problems occurred randomly and did not concern a specific subpopulation of patients.

Results of the acceptability study and the input of 3 independent health-care providers enabled to validate 80 % of learning content and make final adaptations. A schematic representation of the interactions between patient and his/her healthcare provider via MyFIT tool is illustrated in Supplementary Fig. 2.

4. Discussion

An eHealth tool for the acquisition of self-management skills in FIT ("MyFIT") was well accepted, easy to use and showed a positive impact on learning, while integrating several aspects of the use of new technologies and Internet. The success rate was independent of the use of eHealth technologies suggesting that the tool can be offered to different categories of patients. Active implication of the patients enabled us to incorporate users' experience, their needs and attitudes regarding acquisition of self-management skills.

To our knowledge there is no eHealth learning tool offering a structured education for the acquisition of skills for FIT in patients with insulin dependent diabetes. Recently, a mobile phone–based data service to assist DM1 patients on intensive insulin treatment enabling an interaction between patients and health care professionals has been described (Kollmann et al., 2007); however, with no structured educational approach.

Crucial role of support of patients has been emphasized by others while using telehealth approaches (Milcent, 2021), as low knowledge of technology might represent barriers for some patients and limit an efficient use of telehealth (Reed et al., 2020). We have recently identified the gaps in existing research highlighting the need for well-designed studies to guide the future development of the e-health learning strategies in the care of patients with T1D (Statista Research Department, 2021).

We have to acknowledge that the study sample was small. Technical problems during the Covid-19 epidemics did not enable to all patients to complete all learning activities. Ninety percent among the patients who finished all learning activities had the final score on the knowledge tests higher than 78 %, which is suggestive of a good success. To learn the principles of FIT, patients with T1D need to have basic self-management skills. Therefore, to avoid potential sources of bias, only patients with T1D who were receiving intensive insulin therapy for more than 1 year and who were educated in self-management of diabetes were included in the present study.

Despite of a monocentric design of the present study, generalisation of our approach is possible and might facilitate healthcare delivery to a larger group of patients. Indeed, the French authorities postulate the education of patient with T1D to self-management in FIT before any prescription of closed-loop systems. In parallel this approach is predicted to be cost-effective as telemedicine services are reimbursable by Health Insurance in France.

5. Conclusion

The results of this exploratory study suggest that the e-Health tool may be used in further prospective studies to assess its impact on glycemic control and cost-effectiveness as a part of usual care. The concept presented here will be useful to prompt future eHealth interventions in people with T1D or other chronic conditions aiming to increase patients' autonomy and prevent disease-related complications.

Funding

This work was supported by the European Regional Development Fund and the Grand-Est Region funding. The funders had no role in study design, data collection and analysis, preparation of the manuscript, and decision to publish.

7. Authors' Contributions

E.F. (Orcid 0000-0002-5434-7320) made substantial contribution to this work by playing a leading role in the design and the realization of

the study, data collection and analyses, drafting and revising the manuscript; C.F. and H.R. contributed to realization of the study, analysis and interpretation of the data and reviewing and editing the manuscript; E.A. had a significant role in the methodological design, analyses and interpretation of data and in drafting of the manuscript. All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Acknowledgements

The authors thank to all participants for their involvement.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2022.101968.

References:

Arbaugh, J.B., Hornik, S., 2006. Do Chickering and Gamson's seven principles also apply to online MBAs? J. Educ. Online 3 (3), 1–18. https://doi.org/10.9743/JEO.2006.2.4.

Association of American Medical Colleges, 2007. Effective Use of Educational Technology in Medical Education. Colloquium on Educational Technology: Recommendations and Guidelines for Medical Educators. Washington: AAMC. https://store.aamc.org/downloadable/download/sample/sample_id/111/ (accessed 19 March 2022).

Bendik, C.F., Keller, U., Moriconi, N., et al., 2009. Training in flexible intensive insulin therapy improves quality of life, decreases the risk of hypoglycaemia and ameliorates poor metabolic control in patients with type 1 diabetes. Diabetes Res. Clin. Pract. 83 (3), 327–333. https://doi.org/10.1016/j.diabres.2008.11.034.

Bergenstal, R.M., Klonoff, D.C., Garg, S.K., et al., 2013. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N. Engl. J. Med. 369 (3), 224–232. https://doi.org/10.1056/NEJMoa1303576.

DAFNE Study Group, 2002. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. BMJ 325 (7367), 746. https://doi.org/10.1136/bmj.325.7367.746.

Elleri, D., Dunger, D.B., Hovorka, R., 2011. Closed-loop insulin delivery for treatment of type 1 diabetes. BMC Med. 9, 120. https://doi.org/10.1186/1741-7015-9-120.

Feigerlová, E., Oussalah, A., Zuily, S., et al. 2020. E-health education interventions on HbA(1c) in patients with type 1 diabetes on intensive insulin therapy: A systematic review and meta-analysis of randomized controlled trials. Diabetes Metab. Res. Rev. 36(6):e3313. DOI: 10.1002/dmrr.3313.

Fitzpatrick, R., Boulton, M., 1994. Qualitative methods for assessing health care. Qual. Saf. Health Care 3, 107–113. https://doi.org/10.1136/qshc.3.2.107.

Flaus-Furmaniuk A., Feigerlova E., Floriot M, et al, 2017. CA-048 - Le programme éducatif intensifié à l'insulinothérapie fonctionnelle permet d'améliorer l'équilibre glycémique chez les sujets diabétiques de type 1 sur 24 mois de suivi et diminue le nombre d'hospitalisation pour la prise en charge d'hypoglycémie sévère. Diabetes Metab., 43 (2), Supplement, Page A66. https://doi.org/10.1016/S1262-3636(17)30292-6.

Gagnon, M.P., Orruño, E., Asua, J., et al., 2012. Using a modified technology acceptance model to evaluate healthcare professionals' adoption of a new telemonitoring system. Telemed J. E Health 18 (1), 54–59. https://doi.org/10.1089/tmj.2011.0066.

Grimaldi, A., Charpentier, G., Slama, G., 2008. Insulinothérapie fonctionnelle: ou l'insuline à la carte. Elsevier Masson, p. 107 p.

Kirkpatrick, D.L., Kirkpatrick, J.D., 2006. Evaluating Training Programs. The Four Levels. Berrett-Koehler Publishers, San Francisco.

Kollmann, A., Riedl, M., Kastner, P., et al., 2007. Feasibility of a mobile phone-based data service for functional insulin treatment of type 1 diabetes mellitus patients. J. Med. Internet Res. 9 (5), e36. https://doi.org/10.2196/jmir.9.5.e36.

Langendam, M., Luijf, Y.M., Hooft, L., et al., 2012. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst. Rev. 1 (1), CD008101. https://doi.org/10.1002/14651858.CD008101.pub2.

Milcent, C., Zbiri, S. 2021. Use of telehealth: evidence from French teleconsultation for women's healthcare, prior and during COVID-19 pandemic. <halshs-03163281> (accessed 19 March 2022).

OHTAC Public Engagement Subcommittee. Public Engagement for Health Technology Assessment at Health Quality Ontario—Final Report From the Ontario Health Technology Advisory Committee Public Engagement Subcommittee [Internet]. Toronto: Queen's Printer for Ontario; 2015 April. 57 p. Corpus ID: 57771759.

Reed, M.E., Huang, J., Graetz, I., et al., 2020. Patient characteristics associated with choosing a telemedicine visit vs office visit with the same primary care clinicians. JAMA Netw. Open 3, e205873.

Statista Research Department. Internet usage penetration in France 2019, by age group. July 7, 2021. Available from https://www.statista.com/statistics/410850/france-internet-usage-penetration-by-age/ (accessed 19 March 2022).

The Diabetes Control and Complications Trial Research Group, 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N. Engl. J. Med. 329 (14), 977–986. https://doi.org/10.1056/NEJM199309303291401.

von Elm, E., Altman, D.G., Egger, M., et al., 2007. STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Ann. Intern. Med. 147 (8), 573–577. PMID: 18313558.